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DEC 1 8 2009

OFFICE OF PETITIONS

In re Patent No. 7,572,237

Saikley et al.

Issue Date: August 11, 2009

Application No. 10/701,993

Filed: November 4 2003

Attorney Dkt. No. ADCI-011

Title: AUTOMATIC BIOLOGICAL ANALYTE TESTING METER WITH

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INTEGRATED LANCING DEVICE AND :

METHODS OF USE

: DECISION ON REQUEST FOR

: RECONSIDERATION OF

: PATENT TERM ADJUSTMENT

This is in response to the "Request Under 37 C.F.R. \$1.705(d) For Reconsideration Of Patent Term Adjustment", filed October 1, 2009. Patentees request that the patent term be adjusted from 329 days to 558 days.

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Patentees also request that a decision on this request for reconsideration of patent term adjustment be deferred or delayed until after a final decision has been rendered in Wyeth v. Dudas. There is no specific regulatory provision for requesting that a petition under 37 CFR 1.705(d) be held in abeyance.

The request for reconsideration of patent term adjustment is **DISMISSED.**

On August 11, 2009, the above-identified application matured into US Patent No. 7,572,237 with a patent term adjustment of 329 days. This request for reconsideration of patent term adjustment (including the required fee) was timely filed within two months of the issue date of the patent. See 37 CFR 1.705(d).

Patentees request recalculation of the patent term adjustment based on the decision in <u>Wyeth v. Dudas</u>, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentees assert that pursuant

to <u>Wyeth</u>, a PTO delay under 35 U.S.C. §154(b)(1)(A) overlaps with a delay under 35 U.S.C. §154(b)(1)(B) only if the delays "occur on the same day." Patentees maintain that the period of adjustment due to the Three Year Delay by the Office, pursuant to 37 CFR § 1.703(b), 229 days, does not overlap with the 455 day period of adjustment due to examination delay, pursuant to 37 CFR §1.702(a), as these periods do not occur on the same day.

Patentees submit that the total period of adjustment for Office delay is the sum of the period of three-year delay (229 days) and the period of examination delay (455 days) to the extent these periods do not overlap. As such, patentees assert entitlement to a patent term adjustment of 558 days (455 days plus 229 days less 126 days of applicants' delay).

The Office finds that as of the day before the date of the filing of the request for continued examination (RCE) on June 20, 2007, the application was pending three years and 228 days after its filing date (November 4, 2006 to December 20, 2007). An entry of a period of adjustment of 455 days was entered for Office delay. At issue is whether patentees should accrue an additional 228 days of patent term adjustment for the Office taking in excess of three years to issue the patent as well as 455 days for Office failure to take a certain action within a specified time frame (or examination delay).

Patentee's calculation of the period of overlap is inconsistent with the Office's interpretation of this provision. 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

To the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

Likewise, 37 CFR 1.703(f) provides that:

To the extent that periods of delay attributable to the grounds specified in §1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule, 65 Fed. Reg. 56366 (Sept. 18, 2000). See also Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final Rule, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See also Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Req. 34283 (June 21, 2004).

As such, the period for over 3 year pendency does not overlap only to the extent that the actual dates in the period beginning three years after the date on which the application was filed overlap with the actual dates in the periods for failure of the Office to take action within specified time frames.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A) is the filing date November 4, 2003 until the day before the filing of the RCE on June 20, 2007. Prior to the issuance of the patent, 455 days of patent term

adjustment were accorded for the Office failing to respond within a specified time frame during the pendency of the application.

The Office did not delay 455 days and then delay an additional 228 days. Accordingly, 455 days of patent term adjustment for Office delay (not 455 days and 228 days) was properly entered because the entire period of delay of 228 days attributable to the delay under 37 CFR 1.702(b) overlaps with the 455 days attributable to grounds specified in § 1.702(a)(1).

Accordingly, at issuance, the Office properly entered no additional days of patent term adjustment.

In view thereof, the Office affirms that the revised determination of patent term adjustment at the time of the issuance of the patent was 329 (455-126) days.

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

Telephone inquiries specific to this matter should be directed to Charlema Grant, Petitions Attorney, at (571) 272-3215.

/Kery A. Fries/

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